Application/Control Number: 10/627,950 Page 2

Art Unit: 1634

DETAILED ACTION

Reasons for Allowance

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Diane Peng (Reg. No. 54,550) on June 16, 2009.

- The application has been amended as follows:Rejoining claims 10-14 and 21 with claims 1, 6-9, 18-20, 22, 23, and 25.
- 1. (Current Amended) A method for detecting a polymorphism related to a genetic disease in a patient sample nucleic acid, comprising the steps of:

providing the patient sample nucleic acid containing a first <u>locus having a first</u>

<u>polymorphism</u> and a second [loci] <u>locus</u> having a [first and] second polymorphism <u>on a site of a microarray</u>, [respectively,] wherein <u>the first or second polymorphism is related to the genetic disease [at a microarray site];</u>

providing an unlabeled blocker that is complementary to the first locus containing the first polymorphism [related to the genetic disease];

hybridizing the unlabeled blocker with the first locus such that the first polymorphism is blocked by the unlabeled blocker[, wherein] and the second locus is unblocked;

Application/Control Number: 10/627,950

Art Unit: 1634

providing a detectable discriminator that is capable of hybridizing with the second locus containing the second polymorphism and specifically identifying the second polymorphism [related to the genetic disease];

Page 3

hybridizing the detectable discriminator with the second locus containing the second polymorphism [related to the genetic disease]; and detecting the second polymorphism [related to the genetic disease] by detecting the presence of the discriminator at the [microarray] site of the microarray.

- 6. (Current Amended) The method of claim 1, wherein the [microarray] site of the microarray comprises a site of an actively addressable electronic microarray.
- 8. (Current Amended) The method of claim 1, wherein the patient sample <u>nucleic acid</u> is amplified.
- 12. (Current Amended) The method of claim 8, wherein the amplification [includes the] <u>is</u> <u>performed using transcription-based amplification system (TAS).</u>
- 13. (Current Amended) The method of claim 8, wherein the amplification [includes the] <u>is</u> <u>performed using self-sustained sequence replication system (3 SR).</u>
- 14. (Current Amended) The method of claim 8, wherein the amplification [includes the] is $performed\ using\ Q\beta$ replicase amplification system (Q β).
- 18. (Current Amended) The method of claim l, further includes the step of performing a screening step <u>for a number of patient nucleic acid samples.</u>
- 20. (Current Amended) The method of claim 19, wherein the multiple segments containing different loci are affixed to [the same microarray] an identical site of the microarray.

21. (Current Amended) The method of claim 19, wherein the multiple segments containing different loci are affixed to [the]different sites of the microarray.

- 22. (Current Amended) The method of claim 6, wherein the microarray further comprises multiple sites and [the] multiple patient nucleic acid samples are provided on the multiple sites of the microarray.
- 3. The following is an examiner's statement of reasons for allowance:

Claims 1, 6-14, 18-23, and 25 are allowable in light of applicant's amendments filed on March 9, 2009 and the examiner's amendments. The rejections under 35 U.S.C 112, second paragraph and 35 U.S.C 103 have been withdrawn in view of the applicant's arguments filed on March 9, 2009 (see pages 5-7 of applicant's remarks). A discriminator in the specification is defined as "a polynucleotide that selectively binds to a polymorphic region of an amplicon, wherein the region may or may not contain a mutation" (see page 16, second paragraph). The closest prior art in the record is Nerenberg *et al.*, (US 2001/0014449 A1, published on August 16, 2001). Nerenberg *et al.*, do not teach hybridizing the unlabeled blocker with the first locus such that the first polymorphism is blocked by the unlabeled blocker as recited in claim 1. This prior art either alone or in combination with the other art in the record does not teach or reasonably suggest a method for detecting a polymorphism related to a genetic disease in a patient sample nucleic acid which comprises all of the limitations recited in claim 1.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

Application/Control Number: 10/627,950 Page 5

Art Unit: 1634

4. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28,

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz, can be reached on (571)272-0763.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Frank W Lu /, Primary Examiner, Art Unit 1634 June 16, 2009 Application/Control Number: 10/627,950

Page 6

Art Unit: 1634